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Dear Sir or Madam:

As an actively practicing neurosurgeon, I feel I must write to clarify my feelings regarding potential FDA regulations of allograft tissue.

In neurosurgery, we make frequent use of cadaver bone graft for fusion materials. As this graft is sterilized by heat, irradiation or freeze dried technique, it is generally accepted in our field that there is minimal risk to the patient. This has certainly been born out in several decades of practice in my particular group of neurosurgeons. As this is quite a common resource in the field of neurosurgery, it would certainly cause considerable inconvenience and unnecessary expense to impose any sort of regulation on such tissue at this time. Therefore, I feel strongly that the issue should be left as is. I would be glad to expand on my feelings at further length if necessary.

Please feel free to contact me with any questions or comments.

Allen D. Efron, M.D.

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